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1/1 WPIL

Titre

Pure, non-immunogenic Factor=VIII composition preparation - using 2-stage viral inactivation of Factor=VIII solution by treatment with phosphate and detergent followed by heating, used for treating haemophilia

Données de publication

N° publication

EP-812858 A1 19971217 DW1998-04 C07K-014/755 Ger 16p * AP: 1997EP-0109314 19970609 DSR:

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HU9700987 A2 19980302 DW1998-21 A61K-035/16 AP: 1997HU-0000987 19970603

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Résumé

Basic

EP-812858 A Preparation of a non-immunogenic composition (I) containing Factor VIII (F8) comprises:

(a) treatment of a solution of F8 with tri-(n-butyl) phosphate (TNBP) and detergent, and

(b) heat treatment of a freeze-dried material containing F8 at 100 deg. C for 15-120 minutes, such that the residual moisture content after the heat treatment is 0.3-1.8 wt.%.
Also claimed is (I).

USE - F8 is used for treating haemophilia.

ADVANTAGE - (I) containing highly pure, doubly virus-inactivated F8 can be obtained from human blood plasma using a 2-stage virus inactivation and purification process involving no use of stabilisers.

Enveloped and non-enveloped viruses are effectively inactivated. Typically the HIV-1 reduction factor (log 10) is > 16.2. Heat treatment under the present conditions causes no significant activity loss.

F8 is typically enriched by a factor of 104 compared with the starting plasma. (Dwg.0/3)

Déposant & Inventeur(s)

Déposant

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